4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1529]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0138. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reclassification Petitions for Medical Devices

The Federal Food, Drug, and Cosmetic Act (FD&C Act) establishes the following three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (special controls), and class III (premarket approval) (section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). To change a device classification, FDA can initiate a reclassification, or an interested person can petition FDA to reclassify a device based on new information (section 513(e) of the FD&C Act). On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted, changing the reclassification process under section 513(e) of the FD&C Act from rulemaking to an administrative order process. To reclassify a device under section 513(e) of the FD&C Act, FDA must do the following before making the reclassification final: (1) publish a proposed order in the *Federal Register* that includes the proposed reclassification and a summary of the valid scientific evidence that supports the reclassification, (2) convene a device classification panel meeting, and (3) consider comments from the relevant public docket.

FDASIA also amended the provisions of the FD&C Act authorizing FDA to require submission of a premarket approval application (PMA) for a preamendments class III device (referred to as a "call for PMAs"). Preamendments devices are devices that were in commercial distribution before the enactment of the 1976 Amendments. Under the FD&C Act, preamendments devices classified into class III may be marketed upon clearance of a 510(k) submission, and submission of a PMA is not required until FDA has issued a final order requiring premarket approval (section 515(b) of the FD&C Act (21 U.S.C. 360e(b)). As amended by FDASIA, the FD&C Act requires that FDA, in its call for PMAs, publish a proposed order in the *Federal Register*, hold a classification panel meeting, and consider comments on the proposed order (section 515(b) of the FD&C Act, as amended by FDASIA).

Under the FD&C Act, FDA's call for PMAs must, among other things, contain an opportunity for interested persons to request a change in the classification of the device based on

new information (section 515(b)(2) of the FD&C Act). After consideration of comments on the proposed order and findings, FDA must either: (1) finalize the call for PMAs by issuing an administrative order requiring approval of a PMA and publishing in the *Federal Register* findings with respect to: (i) the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed product development protocol and (ii) the benefit to the public from the use of the device; or (2) publish a notice in the *Federal Register* terminating the proceeding and initiate a reclassification proceeding based on new information (section 515(b)(3) of the FD&C Act, as amended by FDASIA; see section 513(e) of the FD&C Act).

The FD&C Act, as amended by FDASIA, now requires the use of administrative orders, rather than rulemaking, when FDA calls for PMAs for a preamendments device remaining in class III (section 515(b) of the FD&C Act, as amended by FDASIA).

FDA refers to a device that was not in commercial distribution before the 1976 Amendments as a postamendments device. Postamendments devices are classified automatically into class III by statute, without any rulemaking process (section 513(f)(1) of the FD&C Act). A postamendments device remains in class III and is subject to the PMA requirements unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II via the De Novo classification process (see section 513(f)(2) of the FD&C Act); or (3) FDA issues an order finding the device to be substantially equivalent to a predicate device that does not require the filing of a PMA (see section 513(i) of the FD&C Act).

FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a postamendments device classified into class III by operation of law (section 513(f)(3) of the FD&C Act). This FDA-initiated reclassification process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the *Federal Register* following consideration of comments and any panel recommendations or comments (§ 860.134(c) (21 CFR 860.134(c))). The reclassification order may, as appropriate,

establish special controls to provide reasonable assurance of the safety and effectiveness of the device (§ 860.134(d)).

Under the 1976 Amendments, Congress classified all those devices previously regulated as new drugs into class III (generally referred to as transitional devices). Under the FD&C Act, FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a transitional device remaining in class III (section 520(l)(2) of the FD&C Act (21 U.S.C. 360j(l)(2)). The process for reclassification of transitional devices initiated by FDA is detailed in 21 CFR 860.136(c). This process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the *Federal Register* following consideration of comments and any panel recommendations or comments.

In the *Federal Register* of September 7, 2021 (86 FR 50132), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 860.123; supporting data for reclassification petitions	6	1	6	497	2,982

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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